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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,899		01/09/2002	Nicholas L. Abbott	02307Z-085840US	3817
43850	7590	04/13/2006		EXAM	INER
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), CA 94306		1639	
				DATE MAIL ED: 04/12/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/044,899	ABBOTT ET AL.
Office Action Summary	Examiner	Art Unit
Requision/Llection	MY-CHAU T. TRAN	1639
The MAILING DATE of this communical Period for Reply	ition appears on the cover sheet wi	th the correspondence address
A SHORTENED STATUTORY PERIOD FOR WHICHEVER IS LONGER, FROM THE MAI - Extensions of time may be available under the provisions of 3 after SIX (6) MONTHS from the mailing date of this communi - If NO period for reply is specified above, the maximum statut - Failure to reply within the set or extended period for reply will Any reply received by the Office later than three months after earned patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF THIS COMMUNIC 37 CFR 1.136(a). In no event, however, may a re- ication. tory period will apply and will expire SIX (6) MON 1, by statute, cause the application to become AB	CATION. eply be timely filed THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).
Status		
 1) Responsive to communication(s) filed 2a) This action is FINAL. 3) Since this application is in condition for closed in accordance with the practice) ☐ This action is non-final. r allowance except for formal matte	
Disposition of Claims		
4)⊠ Claim(s) <u>129-202</u> is/are pending in the 4a) Of the above claim(s) is/are 5)□ Claim(s) is/are allowed. 6)□ Claim(s) is/are rejected. 7)□ Claim(s) is/are objected to. 8)⊠ Claim(s) <u>129-202</u> are subject to restric	withdrawn from consideration.	
Application Papers		
9) The specification is objected to by the E 10) The drawing(s) filed on is/are: a Applicant may not request that any objection Replacement drawing sheet(s) including the second or declaration is objected to be	a) accepted or b) objected to be on to the drawing(s) be held in abeyan be correction is required if the drawing(ce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
*	ocuments have been received. Ocuments have been received in Aporthe priority documents have been all Bureau (PCT Rule 17.2(a)).	pplication No received in this National Stage
Attachment(s) 1) Notice of References Cited (PTO-892)	· —	Summary (PTO-413)
 2) Notice of Draftsperson's Patent Drawing Review (PTC 3) Information Disclosure Statement(s) (PTO-1449 or PT Paper No(s)/Mail Date 		s)/Mail Date nformal Patent Application (PTO-152)

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DETAILED ACTION

Application and Claims Status

- 1. Applicant's amendment and response filed 02/03/2006 are acknowledged and entered. No claims were amended, cancelled, and/or added. Claims 129-202 are currently pending.
- 2. Applicant amendment and response filed 09/19/2005 was acknowledged and entered. Applicant's amendment has the *wrong* status identifiers for claims 129-173, which should be "previously amended" (See 37 CFR 1.121 and MPEP § 714). Applicant elected claims 186-189 with traverse, and elected the following species: a) self-assembled monolayers comprising an alkanethiol as the species of substrate; b) biotin as the species of recognition moiety; c) neutravidin as the species of analyte; and d) 5CB as the species of liquid crystal. *However*, applicant's election of claims 186-189 *does not* correspond to the originally presented invention of claims 1-8 (renumbered as claims 121-128) as required in the *Notice of Non-Responsive Amendment* mailed 06/14/2005. Claim 186 is drawn to a device for amplifying an interaction between a first recognition moiety and an analyte of interest whereas the restricted claim 121 (filed 01/09/2002) is drawn to a device for the detection of ligands. Thus, this election is considered non-responsive and a second *Notice of Non-Responsive Amendment* was mailed 12/16/2005.
- 3. The amendment and response filed 02/28/2005: cancelled claims 1-120 and 121-128 and added new claims 129-202, which is also improper because claims 129-173 were added in the amendment filed 10/18/2004, i.e. the current claims 129-173 are amended not new (see 37 CFR

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1.121 and MPEP § 714). A *Notice of Non-Responsive Amendment* mailed 06/14/2005 was sent because applicant did not 1) present claims corresponding to the originally presented invention of claims 1-8 (renumbered as claims 121-128), and did not 2) elected inventive species (e.g. items A (e.g. organic layer) – E (receptor)) as *required* in the restriction/election mailed on 06/10/2004.

- 4. The amendment and response filed 10/18/2004: "re-insert" claims 7, 10-13, 32-34, 48-54, and 88-101, which is an improper amendment of claims (see 37 CFR 1.121(c)(5) and MPEP § 714); cancelled claims 121-128; and added claims 129-173. A Notice of Non-Compliant Amendment (37 CFR 1.121) mailed 01/19/2005 was sent because the amendment was *improper* (See 37 CFR 1.121 and MPEP § 714).
- 5. The preliminary amendment filed on 01/09/2002: cancelled claims 1-120 and added claims 1-8, wherein these claims are improper numbering of claims. (See 37 C.F.R. 1.126). An Election/Restriction mailed on 06/10/2004 regarding the newly added claims 1-8, which were renumbered as claims 121-128.
- 6. In the telephone interview on 01/24/2006 with the applicant's attorney of record, Mr. Todd Esker, it was agreed upon that the previous restriction and election mailed 06/10/2004 be withdrawn and a new restriction and election be made for the currently pending claims 129-202. (See response filed 02/03/2006 and Interview Summary mailed 01/31/2006). The new restriction and election are as follows.

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Election/Restrictions

7. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 129-143 and 158-162, drawn to a device with the structural combination of a first substrate, a second substrate, a first organic layer, and a mesogenic layer, classified in class 422, subclass 50.
- II. Claims 144-157, drawn to a method of detecting an analyte with the step of detecting the second orientation of the mesogens, classified in class 436, subclass 169.
- III. Claims 163-172, drawn to a device with the structural combination of a first substrate, a second substrate, a first organic layer, a second organic layer, and a mesogenic layer, classified in class 422, subclass 82.05.
- IV. Claims 173-178, drawn to a device with the structural feature of the second recognition moiety attached to the second organic layer, classified in class 435, subclass 287.1.
- V. Claims 179-181, drawn to a device with the structural combination of a first substrate, a mesogenic layer, and an interface, classified in class 422, subclass 99.
- VI. Claims 182-184, drawn to device with the structural combination of a first substrate, a second substrate, a mesogenic layer, and an interface, classified in class 435, subclass 287.8.
- VII. Claim 185, drawn to a method of detecting an analyte with the step of detecting the third orientation of the mesogens, classified in class 436, subclass 55.

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VIII. Claims 186-189, drawn to a device with the structural feature of a first recognition moiety-analyte complex, classified in class 435, subclass 4.

- IX. Claims 190 and 191, drawn to a copper(II)-detecting device, classified in class 436, subclass 80.
- X. Claims 192-195, drawn to a sodium-detecting device, classified in class 436, subclass 79.
- XI. Claims 196-199, drawn to a hexylamine-detecting device, classified in class 436, subclass 111.
- XI. Claim 200, drawn to a method of detecting an analyte with the step of contacting the analyte-recognition moiety complex with a mesogenic layer, classified in class 435, subclass 3.
- XII. Claims 202, drawn to a method of detecting an analyte with the step of contacting the analyte with an organic mesogenic layer, classified in class 436, subclass 164.

The inventions are distinct, each from the other because of the following reasons:

8. Inventions of Groups I, III-VI, and VIII-XI are directed to related apparatuses. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related inventions are distinct because they have materially different design, i.e. different structural features. For example, Group I requires the features combination of a first substrate, a second substrate, a first organic layer, and a mesogenic layer. Group III requires the features combination of a first

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substrate, a second substrate, a first organic layer, a second organic layer, and a mesogenic layer. Group IV requires the feature of the second recognition moiety attached to the second organic layer. Group V requires the features combination of a first substrate, a mesogenic layer, and an interface. Group VI requires the features combination of a first substrate, a second substrate, a mesogenic layer, and an interface. Group VIII requires the feature of a first recognition moiety-analyte complex. Group IX requires the feature of a recognition moiety that recognized copper(II). Group X requires the feature of a recognition moiety that recognized sodium. Group XI requires the feature of a recognition moiety that recognized hexylamine. Moreover, these different structural features results in materially different design of the device and would have different mode of operation and/or effect. Consequently, the related inventions are distinct, i.e. mutually exclusive, and the art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features.

9. Inventions of Groups II, VII, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and effects, i.e. using different steps, requiring different reagents and/or producing different results. For example, Group II requires the steps of detecting the second orientation of the mesogens. Group VII requires the steps of detecting the third orientation of the mesogens. Group XII requires the steps of contacting the analyte-recognition moiety complex with a

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mesogenic layer. Group XIII requires the steps of contacting the analyte with an organic mesogenic layer. These steps require different reagents and producing different results.

Consequently, the different inventions are not disclosed as capable of use together and they have different modes of operation and effects, and the restriction between these groups is proper.

- 10. Inventions of Groups I, III-VI, or VIII-XI (product) and Groups II, VII, XII, or XIII (process) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product such as the method of immunoassay or any of the methods of Groups II, VII, XII, or XIII.
- 11. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.
- 12. This application contains claims directed to patentably distinct species of the claimed invention for Groups I, III-VI, and VIII-XI. Elections of species are required as follows.

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13. If applicant elected the invention of Group I, applicant is required to elect from the following patentably distinct species of a)-h):

- a) A single specific species of 1st substrate (see instant specification pages 23-26).
- b) A single specific species of 2nd substrate (see instant specification pages 23-26).
- c) A single specific species of 1st organic layer (see instant specification pages 30-38).
- d) *If* applicant elected the formula, i.e. (RO)₃-Si-R¹-(X¹)_n, of claim 137 as the as the 1st organic layer, applicant is further requires to specifically define all variable groups of the formula (i.e. all atom and bonds shown).
- e) *If present*, a *single specific species* of 2nd organic layer (see instant specification pages 30-38).
- f) A *single specific species* of 1st recognition moiety (see instant specification pages 30-38, and claims 134, 137, and 162).
- g) If present, a single specific species of 2nd recognition moiety.
- h) A single specific species of mesogenic layer (see instant specification pages 49-50).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 129 and 158 are generic.

- If applicant elected the invention of Group II, applicant is required to elect from the 14. following patentably distinct species of a)-f):
 - a) A single specific species of analyte (see claims 145-148).
 - b) A single specific species of recognition moiety (see claim 149).
 - c) A single specific species of 1st orientation (see claim 152).
 - d) A single specific species of 2nd orientation (see claim 152).
 - e) A single specific species of mode of detection (see claims 153-157).
 - f) A single specific species of mesogens (see instant specification pages 49-50).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 144 is generic.

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15. If applicant elected the invention of Group III, applicant is required to elect from the following patentably distinct species of a)-i):

- a) A single specific species of 1st substrate (see instant specification pages 23-26).
- b) A single specific species of 2nd substrate (see instant specification pages 23-26).
- c) A *single specific species* of 1st organic layer (see instant specification pages 30-38, and claims 166 and 171).
- d) A single specific species of 2nd organic layer (see instant specification pages 30-38, and claims 167 and 172).
- e) A *single specific species* of 1st recognition moiety (see instant specification pages 30-38, and claims 163 and 168).
- f) A single specific species of 2nd recognition moiety (see instant specification pages 30-38, and claims 163 and 168).
- g) A single specific species of analyte (see claims 164 and 169).
- h) A single specific species of interaction (see claims 165 and 170).
- i) A single specific species of mesogenic layer (see instant specification pages 49-50).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

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Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 163 and 168 are generic.

- 16. If applicant elected the invention of Group IV, applicant is required to elect from the following patentably distinct species of a)-i):
 - a) A single specific species of 1st substrate (see instant specification pages 23-26).
 - b) A single specific species of 2nd substrate (see instant specification pages 23-26).
 - c) A *single specific species* of 1st organic layer (see instant specification pages 30-38, and claims 176).
 - d) A single specific species of 2nd organic layer (see instant specification pages 30-38, and claims 177).
 - e) A single specific species of 1st recognition moiety (see instant specification pages 30-38, and claim 173).
 - f) A single specific species of 2nd recognition moiety (see instant specification pages 30-38, and claim 173).
 - g) A single specific species of analyte (see claim 174).
 - h) A single specific species of interaction (see claim 175).
 - i) A single specific species of mesogenic layer (see instant specification pages 49-50).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species

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have different issues regarding patentability and represent patentably distinct subject matter.

Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 173 is generic.

- 17. If applicant elected the invention of Group V, applicant is required to elect from the following patentably distinct species of a)-d):
 - a) A single specific species of 1st substrate (see instant specification pages 23-26).
 - b) A single specific species of mesogenic layer (see instant specification pages 49-50).
 - c) A single specific species of interface (see claim 179).
 - d) A *single specific species* of attachment between the recognition moiety and the 1st substrate (see claims 180 and 181).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

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Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 179 is generic.

- 18. If applicant elected the invention of Group VI, applicant is required to elect from the following patentably distinct species of a)-e):
 - a) A single specific species of 1st substrate (see instant specification pages 23-26).
 - b) A single specific species of 2nd substrate (see instant specification pages 23-26).
 - c) A single specific species of mesogenic layer (see instant specification pages 49-50).
 - d) A single specific species of interface (see claim 182).
 - e) A *single specific species* of attachment between the recognition moiety and the 1st substrate (see claims 183 and 184).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 182 is generic.

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19. If applicant elected the invention of Group VIII, applicant is required to elect from the following patentably distinct species of a)-d):

- a) A single specific species of 1st substrate (see instant specification pages 23-26).
- b) A single specific species of 1st organic layer (see instant specification pages 30-38).
- c) A single specific species of mesogenic layer (see instant specification pages 49-50).
- d) A single specific species of analyte (see claim 188).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 186 is generic.

- 20. If applicant elected the invention of Group IX, applicant is required to elect from the following patentably distinct species of a)-d):
 - a) A single specific species of 1st substrate (see instant specification pages 23-26).
 - b) A single specific species of 2nd substrate (see instant specification pages 23-26).
 - c) A single specific species of 1st organic layer (see instant specification pages 30-38).

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d) A single specific species of mesogenic layer of the formula (X), i.e.

$$R^{11}$$
, and applicant is further requires to specifically

define all variable groups of the formula (i.e. all atom and bonds shown).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 190 is generic.

- 21. If applicant elected the invention of Group X, applicant is required to elect from the following patentably distinct species of a)-d):
 - a) A single specific species of 1st substrate (see instant specification pages 23-26).
 - b) A single specific species of 2nd substrate (see instant specification pages 23-26).
 - c) A single specific species of 1st organic layer (see instant specification pages 30-38).

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d) A single specific species of mesogenic layer of the formula (X), i.e.

define all variable groups of the formula (i.e. all atom and bonds shown).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 192 is generic.

- 22. If applicant elected the invention of Group XI, applicant is required to elect from the following patentably distinct species of a)-d):
 - a) A single specific species of 1st substrate (see instant specification pages 23-26).
 - b) A single specific species of 2nd substrate (see instant specification pages 23-26).
 - c) A single specific species of 1st organic layer (see instant specification pages 30-38).

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d) A single specific species of mesogenic layer of the formula (X), i.e.

define all variable groups of the formula (i.e. all atom and bonds shown).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect *a single disclosed species* of the above species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 196 is generic.

- 23. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- 24. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

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allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

25. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

My-Chau T. Tran
April 7 2006

April 7, 2006